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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,445	06/26/2001	Yunhua N. Jeng	11916.0048.NPUS00(MOPV048	6324

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07/22/2003

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EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 07/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/891,445

Applicant(s)

JENG ET AL.

Examiner

Roy Teller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14. 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/23/03 has been entered.

Claims 1, 2, and 4-22 are pending.

Information Disclosure Statement

The information disclosure statement filed 6/23/04 (Paper No: 14) is acknowledged. A signed copy is attached hereto.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, and 4-22 under 35 USC 103(a) is maintained.

In claims 1, 4, 5, and 8-22, applicant argues that there is no motivation to combine Magruder (USPN 5,037,420) with Mitchell (USPN 5,474,980) in order to arrive at the claimed invention.

The claimed invention is drawn to a composition of matter comprising human, equine, bovine or porcine somatotropin (ST) and a first bioavailability enhancing constituent (BEC)

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comprising a non-ionic surfactant and a second BEC comprising a non-reducing carbohydrate and/or an oxo-acid salt where the somatotropin and BEC are in a non-aqueous carrier. Dependent claims recite the first BEC present from about 0.1% to about 10% by weight of the composition and the second BEC from about 1% to about 20% by weight of the composition. The first BEC comprises a non-ionic surfactant. The second BEC contains a selection of oxo-acid salts.

Margruder and Mitchell teach the elements of the claimed invention, see *supra*. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formulated the composition disclosed by Magruder in the biocompatible oil/aluminum monostearate vehicles taught by Mitchell because Mitchell teaches that the oil/monostearate vehicles are useful for prolonged parental release of somatotropin *in vivo*.

Applicant further argues that there are no teachings or suggestion of benefits envisioned from the combination of Magruder with Mitchell. The benefit is outlined by Mitchell, when he teaches that the oil/monostearate vehicles are useful for prolonged parental release of somatotropin *in vivo*.

In claim 2, applicant argues that Scarborough (USPN 6,162,258) adds nothing to the combination of Magruder and Mitchell. In fact, Scarborough teaches a polyoxyethylene sorbitan fatty acid ester and a polyoxyethylene fatty acid ester mixed with a growth hormone such as somatotropin, see *supra*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the non-ionic surfactants of Scarborough to the composition disclosed by Magruder in view of Mitchell in order to enhance the bioavailability of somatotropin in the composition, because Scarborough teaches biocompatibility in the healing response, see *supra*.

In claims 6 and 7, applicant argues that a non-aqueous carrier is not taught by Hamilton (USPN 4,816,568). The claimed invention is as described above, wherein the BEC is a non-reducing carbohydrate selected from one polyol and one carbohydrate ester, which include: tehalose, sucrose, mannitol, sorbitol, trehalose octaacetate, trehalose dihydrate, sucrose octaacetate, and cellobiose octaacetate.

Hamilton teaches the elements of the claimed invention, see *supra*. Hamilton teaches a stabilized growth hormone formulation that can be compressed into a tablet or pellet form. When combined with the teachings of Magruder and Mitchell it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the polyol stabilizer of Hamilton to the composition disclosed by Magruder in view of Mitchell in order to enhance the bioavailability of the somatotropin in the composition, because Hamilton teaches that growth hormones may be admixed with various stabilizers to provide for the preservation of the soluble bioactivity of the growth hormone.

Conclusion

All claims are rejected.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is (703) 305-4243. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RT
1654
7/22/03

RT



CHRISTOPHER R. TATE
PRIMARY EXAMINER